IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LIGITATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO PLAINTIFFS: **All Wave II TVT Cases** **Jean Fleck v. Ethicon, Inc., et. al.** **Case No. 2:12-cv-01681** **Phyllis Martin v. Ethicon, Inc., et. al.** **Case No. 2:12-cv-02029** **Ramona Phillips v. Ethicon, Inc., et. al.** **Case No. 2:12-cv-02143**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION TO EXCLUDE THE GENERAL OPINION TESTIMONY OF JANET E. TOMEZSKO, M.D.

I. PRELIMINARY STATEMENT

Now come Plaintiffs seeking to exclude, or to limit in the Court's discretion, the expert testimony of Dr. Janet E. Tomezsko, M.D. ("Dr. Tomezsko"), pursuant to Federal Rule of Evidence ("Rule") 702 and the standards set forth by the United States Supreme Court in *Daubert v. Merrell Dow Pharms. Inc.* 509 U.S. 579 (1993) and as adopted by the Fourth Circuit. *See Bryte v. Am. Household, Inc.*, 429 F.3d 469, 476 (4th Cir. 2005)(federal law governs the admissibility of expert testimony). Dr. Tomezsko seeks to offer general opinions regarding the TVT sling ("TVT") manufactured and marketed by Defendant Ethicon, Inc. ("Ethicon") for the treatment of stress urinary incontinence ("SUI"). Her opinions are proffered in the TVT Expert Report of [Dr.

Tomezsko] ("Tomezsko Report")[1] and in her deposition testimony of June 27, 2016.[2] Plaintiffs now seek to exclude or limit Dr. Tomezsko's opinions regarding the TVT as set forth herein such that:

- she cannot "cherry-pick" or otherwise proffer opinions based solely on her selective review of reliance materials;
- she is unqualified to proffer any opinions about the legal adequacy of the warnings in the instructions for use ("IFU") accompanying the TVT to the extent she intends to proffer any;
- her opinion that removing TVTs in their entirety are "rare" is based on mere *ipse dixit* and must be excluded;
- her opinions based on data regarding devices other than the TVT are outside the scope of her opinion here and must be excluded; and
- Dr. Tomezsko testified on the record as follows and her opinions must be so limited at trial regarding:
    - that there are no long-term randomized studies of the TVT where safety was the "primary end point" of the study;
    - that there are no long-term randomized studies of the TVT where the TVT was found "safe and effective" and where dyspareunia was tracked as either the primary or secondary end point of the study;
    - that she is unsure whether a TVT can be removed in its entirety and that to do so requires "aggressive dissection;"
    - that mesh can curl, rope or fray.

[1] The Tomezsko Report is attached hereto as Exhibit A. Citations to the Tomezsko Report are in the form (Ex. A, ___.).

[2] Relevant excerpts of Dr. Tomezsko's deposition of June 27, 2016 are attached hereto as Exhibit B. Citations to it will be in the form (Ex. B, ___:___; ___;___.)

II. LEGAL STANDARD

Rule 702 states:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> (b) the testimony is based on sufficient facts or data;
> (c) the testimony is the product of reliable principles and methods; and
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Rule 702.

The Supreme Court in *Daubert* assigned to district courts a "gatekeeping function" in determining whether expert testimony is both reliable and relevant and, thus admissible, under Rule 702. 509 U.S. 579. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152; *see also Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001)("Under [Rule] 702, trial judges act as gatekeepers to ensure that any and all scientific testimony . . . is not only relevant, but reliable,") (internal citations and quotations omitted.). Under both *Daubert*, 509 U.S. 579, and Rule 104(a) -- the statute imposing a duty on courts to decide preliminary questions regarding the qualifications of witnesses and/or the admissibility of evidence -- this Court must determine whether the requirements of Rule 702 are met before any expert testimony can be presented to the jury. *See*, *Cooper*, 259 F.3d at 199; (the district court determines whether the methodology employed by the expert is "scientifically valid" and whether that methodology is applicable to the facts in issue). While *Daubert* requires Rule 702 to be applied flexibly, unfettered admissibility is not the standard and "the proponent of the testimony must establish its admissibility by a preponderance of proof." *See Cooper*, 259 F.3d at 199 (citing to *Daubert*, 509 U.S. at 592 n. 10; *see also Hines v. Wyeth*, C. A. No. 2:04-0690, 2011 WL 2792436 at *2 (S.D.W.Va. July 14, 2011).).

III. LEGAL ARGUMENT

A. DR. TOMEZSKO'S OPINIONS MUST BE EXCLUDED TO THE EXTENT THAT THEY ARE GROUNDED SOLELY IN DR. TOMEZSKO'S SELECTIVE REVIEW OR CHERRY-PICKING OF THE RELEVANT SCIENTIFIC SCHOLARSHIP AND DO NOT ACCOUNT FOR EXTENSIVE SCHOLARSHIP CONTRADICTING DR. TOMEZSKO'S OPINIONS.

This Court has previously held that expert witnesses may not ground their opinions in merely a selective review of academic or scientific literature, choosing only materials that support their opinions, while ignoring literature that does not. Such an approach is unreliable under *Daubert* and its progeny:

> An expert's opinion may be unreliable if he fails to account for contrary scientific literature and instead selectively chooses his support from the scientific landscape. If the relevant scientific literature contains evidence tending to refute the expert's theory and the expert does not acknowledge or account for that evidence, the expert's opinion is unreliable.

Wilkerson v. Boston Scientific Corp., C. A. No. 2:13-cv-04505, 2015 WL 2087048 at *9 (S.D.W.Va May 5, 2015)(internal citations and quotations omitted.); *see also Kumho Tire Co.*, 526 U.S. at 152.

Dr. Tomezsko engages in just such cherry-picking of scientific evidence in her attempt to support some of her opinions, while she ignores scientific scholarship refuting them.

Specifically, Dr. Tomezsko engaged in selective review of materials regarding her opinions about whether inflammation stemming from TVT implants is clinically significant. Dr. Tomezsko's opinions must be excluded. *See Kumho Tire*, 526 U.S. at 152; *see also Wilkerson*, 2015 WL 2087048 at *9.

Dr. Tomezsko's deposition testimony makes it apparent that she either took no note of, or certainly did not countenance, any literature opposing her opinion that the chronic inflammation attendant to the implant of transvaginal mesh devices, including the TVT, has no clinical effect.

(Ex. B, 49:16-18.) Opinions such as the following must be excluded for failing to "account for contrary scientific literature." *See Wilkerson*, 2015 WL 2087048 at *9:

> Q. Are you aware of any peer-reviewed literature that suggests that the type of polypropylene mesh contained in the TVT Retropubic device can result in chronic inflammation, whether you agree with that or not?
>
> A. Again, I look at the literature for what it proves, not what it suggests. So when you say am I aware of the "suggests," I really look at the literature for what is proven, and the literature does not show any chronic inflammation in the Level 1 evidence.
>
> Q. Are you aware of any literature that suggests that the type of polypropylene mesh used in the TVT Retropubic can cause chronic inflammation? Are you at least aware of that literature?
>
> * * * *
>
> A. I would guess there is something out there, and you can show it to me specifically if there is something you want me to specifically look at.

(Ex. B, 49:21-50:18.)

In short, despite agreeing that contrary evidence exists, Dr. Tomezsko makes it plain that she made no attempt to review those materials prior to proffering her opinion that the inflammation that accompanies the implant of mesh has no clinical effect. Her opinion is unreliable because she did not account for scholarship contrary to hers and her opinions must be excluded. *See Wilkerson*, 2015 WL 2087048 at *9.

B. DR. TOMEZSKO IS NOT QUALIFIED TO OFFER OPINIONS ABOUT THE LEGAL ADEQUACY OF THE IFU ACCOMPANYING THE TVT.

Dr. Tomezsko is a board certified urogynecologist (Ex. A, 1) who lacks special qualifications in law or regulatory matters. (*Id*.) As this Court has previously held, medical experts are not qualified to offer opinion regarding the adequacy of a corporate defendant's IFU that accompanies a mesh device when marketed, based only on their own experience. *See Sederholm*

v. Boston Scientific Corp., C. A. No. 2:13-cv-12510, 2016 WL 3282587 at *13 (S.D.W. Va. June 14, 2016)(excluding urologist's expert opinions on the adequacy of defendant's IFU that he based solely on the risks he observed in his practice.). Dr. Tomezsko offers just such opinion in the Tomezsko Report (Ex. A, 23-24)(offering, among other things, that the TVT IFU "presents the risks of the device which would not otherwise be known by pelvic surgeons."). Dr. Tomezsko is not qualified to offer an opinion regarding the legal adequacy of an IFU and her opinions must be excluded to the extent she proffers them herein.

C. DR. TOMEZSKO'S OPINION THAT OCCASIONS WHERE MESH DEVICES CANNOT BE REMOVED ENTIRELY ARE "RARE" IS BASED ON *IPSE DIXIT* AND MUST BE EXCLUDED.

Dr. Tomezsko testified that she would not identify on the record any physicians who had removed entire retropubic devices (such as the TVT) because the procedures are performed "so rarely" that identifying such surgeons could potentially reveal their patients' identities. (See Ex. B, 62:14-23.) Frankly, this testimony can be interpreted in two distinct ways. First, it is in fact, nearly impossible to remove implanted TVT devices, making such occasions technically "rare." Dr. Tomezsko admitted as such on the record:

> Q. Doctor, would you agree that removing an entire TVT Retropubic device may require aggressive dissection?
>
> A. Yes, I would.
>
> Q. And, Doctor, would you agree that there is no guarantee a surgeon would be able to remove an entire TVT device in the event it needed to be removed?
>
> * * * *
>
> A. I agree.

(Ex. B, 64:8-17.)

Q. Doctor, do you believe that the entire TVT Retropubic device can be removed after it's ingrown into a woman's tissues?

A. I believe that you can attempt to remove the entire device, and I'm not sure, on a microscopic level, that you can remove the entire device.

(*Id*., 61:10-16.)

Second, even taking Dr. Tomezsko's testimony that entire explants are conducted "so rarely" in the spirit she likely intended, Plaintiffs move to exclude Dr. Tomezsko's opinion as classic *ipse dixit*. She offers no support, whatsoever, for her opinions that the need to remove TVTs entirely are so rare that even revealing the names of the surgeons performing such procedures risks exposing the identities of their patients. She expects this Court to accept her opinion simply because she says it is so. Such will not pass muster under applicable law and must be excluded. *See Huskey*, 29 F.Supp.3d at 725 (excluding opinion of defendant's medical expert about mesh's biocompatibility and tendency not to degrade as based on mere "*ipse dixit*.").

D. DR. TOMEZSKO CANNOT SUPPORT HER OPINIONS REGARDING THE TVT WITH DATA REGARDING OTHER DEVICES.

Dr. Tomezsko relies heavily on the 2015 Cochrane Report to support her opinion that the TVT is safe and effective. By her own admission, the Cochrane Report includes data from the TVT but also from other devices entirely. (*See*, Ex. B, 123:1-128:10.) To the extent that Dr. Tomzsko seeks to support her opinions regarding the TVT with studies and/or data concerning other devices, such is unreliable and must be excluded. *See Huskey v. Ethicon*, C. A. No. 2:12-cv-05201, 2014 WL 2861778 at *5 (S.D.W. Va. August 6, 2014).

E. SOME OF DR. TOMEZSKO'S OPINIONS WERE LIMITED BY HER DEPOSITION TESTIMONY AND SHOULD REMAIN SO AT TRIAL.

Dr. Tomezsko testified on the record as follows:

- that there are no long-term randomized studies of the TVT where safety was the "primary end point" of the study; (Ex. B, 57:21-58:6)

- that there are no long-term randomized studies of the TVT where the TVT was found "safe and effective" and where dyspareunia was tracked as either the primary or secondary end point of the study; (*id*., 58:7-61:4)

- that she admitted on the record that she is unsure whether a TVT can be removed in its entirety and that to do so requires "aggressive dissection"; (*id*., 61:10-16; 64:8-17)

- that she testified on the record that mesh can curl, rope or fray under tension. (*Id*.., 85:2-5.)

Dr. Tomezsko's opinions at trial must be limited to her testimony.

IV. CONCLUSION

For reasons of the forgoing, the general opinions testimony of Dr. Tomezsko, as set forth herein, must be excluded as required by federal law.

Respectfully submitted,

Date: July 21, 2016

By: /s/Fidelma L. Fitzpatrick

Fidelma L. Fitzpatrick
Motley Rice LLC
321 South Main Street
Providence, RI 02903
Phone: (401) 457-7700
Fax: (401) 457-7708
ffitzpatrick@motleyrice.com

Fred Thompson, III
Motley Rice LLC
28 Bridgeside Blvd.
Mount Pleasant, SC 29464
Phone: (843) 216-9000
Fax: (843) 216-9450
fthompson@motleyrice.com

Counsel for Plaintiff